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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,537	02/23/2004	Wadih Arap	UTSC:872US	2636

7590 03/30/2007

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EXAMINER	
LI, BAO Q	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/784,537	ARAP ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2, 4, 7- 21, 48-55, 64-69* is/are pending in the application.

4a) Of the above claim(s) *10-19 and 53-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,7-9 and 20* is/are rejected.

7)☒ Claim(s) *20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/09/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This is a response to the amendment filed on Dec. 22, 2006. Claims 2, 4, 7, 8, 9, 13, 20-21, 48-54, have been amended. Claims 1, 3, 5-6, 22-47, 56-63 have been canceled. New claims 64-69 have been added. Claims 2, 4, 7- 21, 48-55, 64-69 are pending. Claims 10-19, 53-55 are withdrawn from consideration. Claims 2, 4, 7-9, 20-21, 48-52, and 64-69 are considered before the examiner.

Claim Rejections - 35 USC § 112 end paragraph

Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

1. The rejection of claims 48-52 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, has been moved necessitated by applicants' amendment filed on Dec. 22, 2006.

Claim Rejections - 35 USC § 102

Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

2. The rejections of claims 1-2, 20, 48-50 under 35 U.S.C. 102(b) as being anticipated by Quik et al. (Brain Res. Bull. 1987, Vol. 19, No. 1, pp. 145-147) or under 35 U.S.C. 102(a) as being anticipated by Georgiadis et al. (Biochemistry, Feb. 2000, Vol. 39, pp. 1152-1155) or under 35 U.S.C. 102(a) as being anticipated by David et al. (J. Med. Chem, Dec. 1999, Vol. 42, pp. 5197-5211) have been withdrawn necessitated by applicants' amendment filed on Dec. 22, 2006.

. Claim Rejections - 35 USC § 1121st paragraph

Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

3. The rejection of claims 3 and 5-6 under 35 U.S.C. 112, first paragraph has been removed since applicants canceled the rejection claims.

Upon reconsidering the pending clams, new ground rejections are made on the record set forth below:

New Ground objection and rejections:

Claim Objection

4. Claim 20 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case, claim 20 fails to further limit claim 4, 7 or 8. Because none of claims 4, 7 and 8 are directed to an antibody, whereas, claim 20 is not only directed to the pharmaceutical composition comprising the peptide cited in claim 4, 7 or 8, it is also directed to an antibody selectively binds to aminopeptidase A (APA). To this context, it enlarges the scope of the independent claim 4, 7 and 8.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 2, 7-9, 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, applicants do not have possession for any other aminopeptidase binding peptides except the identified SEQ ID NOS: 1-6.

7. Whether applicants have a possession of the claimed invention is related to the factors set forth below: 1). Level of skill in the art; 2). Method of making it; 3). Complete or partial

structure; 4). Physical and/or biological properties; and 5). Correlation between structure and function.

8. In the instant case, the rejected claims are drawn to a genus of peptides capable of specifically binding to aminopeptidase A. Applicants teaches to use an in vivo phage display model to randomly identify peptides of SEQ ID NOS: 1-6 that bind APA. The specification does not teach with any degree of peptide sequence structure homology or identity particularly among the members of these family of peptides. The genus of these peptides may encompass numerously large quantity of undefined amino acid sequences as claims drafted. However, specification fails to reasonably convey to the skilled artisan that Applicants had possession of the claimed invention at the time the application was originally filed. Applicants only teach limited species of 6 peptide molecules that are deemed capable of binding APA, but no other information was provided. One skilled in the art could not immediately recognize or distinguish members of the genus of the such peptides as claims drafted.

9. MPEP § 2163.02 states, "[a] n objective standard for determining compliance with the written description requirement is "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided: The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. In the instant case, since there is no teaching regarding the relationship between the structure and function of the generically claimed peptide, one skilled in the art could not immediately recognize or distinguish members of the genus of the claimed peptide molecules that are deemed capable of exhibiting the same claimed activity as claims drafted. Applicants are not considered to have possession for the generically claimed peptides.

10. Moreover, because the claimed genus peptides encompass large quantity of the undefined peptides, an adequate written description of the claimed invention must include a sufficient description of at least representative numbers of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicants were in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been shown by Applicants in the current specification; nor have

Applicants shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicants were in possession of the claimed genus at the time the application was filed..

11. Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of peptide sequences, the skilled artisan could not immediately recognize or distinguish members of the claimed genus of peptides with defined structures.

12. To this context, the full breadth of the claims does not meet the written description provision of 35 U.S.C. 112, first paragraph, Applicants are not considered to have the possession of the claimed genus of peptides.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

14. Claim 20 is rejected under 35 U.S.C. 102(a) as being anticipated by Mentzel et al. (Kidney International. 1999, Vol. 55, pp. 1335-1347).

15. A broad reasonable interpretation of the antibody cited in claim 20 is directed to any antibody that can selectively bind to APA.

16. Mentzel et al. teach two monoclonal antibodyies ASD-3/37 and ASD-37/41 that selectively bind to APA. Mentzel et al. also teach to administering 4 mg of said antibodies via intravenously injection into mice induce a massive albuminuria. While the reference does not explicitly teaches that the antibodies are in a composition, it implicitly cites that the antibodies are injected as a pharmaceutical accepted composition intravenously. Because the reference teaches that the control animals are only injected with control saline and it is well known in the art that the injecting composition intravenously is necessarily required to be in a pharmaceutical

accepted liquid formulation (See page 1337). To this context, the claim is anticipated by the cited reference.

Conclusion

Claims 4, 21, 48-52, 64-69 are free of rejections. However they would not be allowed until the issues of other rejected claims are resolved.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Baoqun Li

Bao Qun Li

BAOQUN LI, MD
PATENT EXAMINER

March 28, 2007